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## Motion

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF NEW YORK

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3 ENDO PHARMACEUTICALS INC,

4 Plaintiff,

New York, N.Y.

5 v.

12 Civ. 8985 (TPG)

6 ACTAVIS INC, et ano.,

7 Defendants.

8 -----x

9 ENDO PHARMACEUTICALS INC,

10 Plaintiff,

New York, N.Y.

11 v.

13 Civ. 3288 (TPG)

12 ROXANE LABORATORIES, INC.,

13 Defendant.

14 -----x

15 September 12, 2013

11:48 a.m.

16 Before:

17 HON. THOMAS P. GRIESA,

18 District Judge

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APPEARANCES

DECHERT LLP

Attorneys for Plaintiff

BY: MARTIN J. BLACK

ROBERT D. RHOAD

HOLLAND & KNIGHT LLP (NY)

Attorneys for Defendant Actavis Inc.

BY: CHARLES ALAN WEISS

NICHOLAS PETER CHIARA

ERIC HAROLD YECIES

LOCKE LORD LLP

Attorneys for Defendant

Roxane Laboratories, Inc.

BY: ALAN B. CLEMENT

KEITH D. PARR

WASIM K. BLEIBEL

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1 THE CLERK: Endo Pharmaceuticals versus Actavis and  
2 Endo Pharmaceuticals v. Roxane Laboratories.

3 THE COURT: OK. We are going to run until about  
4 12:30, I guess a little after that. Who wants to present what?

5 MR. BLACK: Your Honor, it's plaintiff's motion for a  
6 preliminary injunction. When we were here before, your Honor  
7 suggested that we take up the issue of the defendants' license  
8 defenses to try to clear that out, and today is the hearing on  
9 that issue.

10 The briefs have been submitted, declarations have been  
11 submitted, and the question before the Court is whether or not  
12 their license defense is so strong that it would preclude us  
13 from getting preliminary injunctive relief. We think that the  
14 licenses themselves are quite clearly not express licenses to  
15 the patents in suit and that their implied license theory is  
16 contrary to the agreement, the negotiating history --

17 THE COURT: Well, there were licenses.

18 MR. BLACK: That is correct, your Honor. And the  
19 question before the Court is whether those licenses, which call  
20 out specific patents, that they had the rights to use, covered  
21 also patents which issued after the prior litigation had  
22 settled and in one case a patent which Endo acquired after the  
23 license had been entered into. These agreements were  
24 explicitly negotiated between the parties, and the patents to  
25 be included in the agreements were explicitly negotiated.

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1           The defendants' positions with respect to what  
2 patents --

3           THE COURT: Why weren't their licenses -- the new  
4 patents are not, you know, the difference of night and day.  
5 They are very similar, are they not?

6           MR. BLACK: No. They are actually very different,  
7 your Honor.

8           THE COURT: They are very different?

9           MR. BLACK: They are very different.

10          THE COURT: What are the differences?

11          MR. BLACK: The '482 patent, which is applicable to  
12 Actavis, it relates to the underlying chemical -- active  
13 chemical ingredient, oxymorphone, a particular way of producing  
14 an oxymorphone that is pure in form.

15          The other two patents relate to what's called  
16 dissolution profile --

17          THE COURT: The patents that were licensed, what were  
18 they about?

19          MR. BLACK: The patents that were licensed related to  
20 specific formulation for a product which in the case of the  
21 defendants included their product. However, your Honor -- and  
22 this is the important point --

23          THE COURT: You are not really answering my question.

24          MR. BLACK: The issue here, your Honor, it all goes  
25 back to the '250 patent. Maybe it will be helpful -- I have a

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1 chart that shows the patents' relationships. Would it be  
2 helpful for me to --

3 THE COURT: It certainly would.

4 MR. BLACK: Thank you, your Honor.

5 If you take a look at slide 8, your Honor, this  
6 encapsulates the issues in the case.

7 THE COURT: Where are you?

8 MR. BLACK: This is the rather busy chart with boxes  
9 and patents on it.

10 THE COURT: What page?

11 MR. BLACK: Page 8.

12 THE COURT: Oh, page 8. All right.

13 MR. BLACK: Page 8.

14 THE COURT: OK.

15 MR. BLACK: OK. So this is what you would call a  
16 patent family tree, which shows relationships between patent  
17 applications. The patent at the top in yellow, the '250  
18 patent, that was a patent that was owned by Endo at the time of  
19 the prior litigation but which all the parties agreed did not  
20 cover the defendants' products. Now, I want to stress that.  
21 It was agreed that it did not cover the defendants' products.  
22 We never sued on that patent. And when we settled the  
23 litigation over the patent we did sue on, we said, fine, we  
24 haven't sued you on this '250 patent. It requires five  
25 different ingredients, none of which are in your products, and,

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1 fine, we'll agree not to sue you in the future on it because  
2 you don't infringe.

3 The defendants also said that they would like licenses  
4 to patents that are called continuations, or claim priority to  
5 the '250 patent. And the reason for that is that a patent in  
6 existence, if it's still being prosecuted in the Patent Office,  
7 you can file what's known as a continuation patent, continue  
8 prosecution, and get additional claims, but the continuation  
9 has to be the same invention and the claims are often almost  
10 identical or virtually identical.

11 And so it was quite logical -- and, indeed, it is  
12 quite common to handle it this way -- the parties agreed that  
13 the '250 patent, which we said didn't even cover their product,  
14 that we agreed that any patents which were continuations of the  
15 '250 would also fall within the scope of their rights. And  
16 that's what was agreed to in the prior litigation. It was a  
17 patent that we all agreed didn't cover their product.

18 Today we have two patents that, in green, on the  
19 bottom here, your Honor, the patents in suit, the '122 and the  
20 '216, that we say does cover their product. There couldn't be  
21 more of a difference with respect to the scope of the claims  
22 than a patent which we all agreed didn't cover the product.

23 THE COURT: I thought you were going to describe what  
24 was licensed.

25 MR. BLACK: What was licensed, your Honor, was the

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1 '250 patent, in yellow, and continuations. We have arrows  
2 showing the sort of family relationship here. So if you think  
3 of, and the patent lawyers often talk about --

4 THE COURT: What is the '250 patent?

5 MR. BLACK: That was a patent that related to a  
6 sustained release drug with a base that had five specific  
7 ingredients. It had xanthan gum, locust bean gum and three  
8 other ingredients in it, none of which were in the defendants'  
9 product. So we never asserted that their products ever  
10 infringed that patent.

11 And when we settled the case over the --

12 THE COURT: What were their licenses?

13 MR. BLACK: They have a license on the '250, and they  
14 have a license on the patent that we litigated, which just  
15 expired, but that's irrelevant to this dispute. It has not  
16 been asserted to be a basis for any relief in this case.

17 THE COURT: I'm sure I'm asking something that is  
18 probably infantile, but I'll ask anyway.

19 They did not -- "they" being the defendants -- did not  
20 infringe '250, right?

21 MR. BLACK: That is correct.

22 THE COURT: But you say there was a license?

23 MR. BLACK: We gave them a covenant not to sue. When  
24 we settled the original case -- I'll have to back up one more  
25 step, your Honor. I'm sorry.

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1           This area of the law, we have so much jargon. But  
2           there is something called the Orange Book, which is a book  
3           that's kept at the FDA. It used to actually be an Orange Book;  
4           today it is, of course, on the computer. And when someone like  
5           Endo gets a product issued by the FDA approved, they list the  
6           patents on the Orange Book to give notice to the public. And  
7           when a generic comes along and says they'd like to make a  
8           generic, the generic has to provide a certification to the FDA  
9           that says we don't infringe those patents, or those patents are  
10          invalid, and when that happens we have litigation.

11          Now, Endo's position, they certified to all the  
12          patents. One of the patents they did infringe and we sued them  
13          on. The '250, though, had five specific ingredients that were  
14          not in their products. And they wrote us a letter and said,  
15          hey, these ingredients aren't in our products, we don't  
16          infringe. We looked at it and said, you are right. So we  
17          never had any litigation over the patent.

18          When we settled the case over the patent we were suing  
19          them on, they said, you know what, for, you know, belt and  
20          suspenders, we want a covenant that you are never going to sue  
21          us on this '250 patent. We said, fine. We've already told you  
22          that you don't infringe and so we'll put it in a license. And  
23          they said, well, we want to make sure that if there is  
24          continuations of the '250, that those are covered also. And we  
25          said, fine. You know, that's -- we had absolutely no dispute



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1 about the '250.

2 Today we have a dispute because there are two other  
3 patents that have different disclosure in them, that have  
4 different inventions, and which on this preliminary injunction  
5 proceeding the defendants have not contested infringement.

6 I want to make this clear. The '250 patent, everybody  
7 agreed they didn't infringe. And when we settled the original  
8 case we said, fine, we're not going to sue you on it. And now  
9 we've got new patents that they do infringe and they don't even  
10 deny infringing and we'd like to proceed, and their position is  
11 that those patents are licensed.

12 THE COURT: Their position is that their patents?

13 MR. BLACK: Their position is that we are barred from  
14 suing them on these newly issued patents that they do infringe  
15 as a result of those patents' relationship to the '250, which  
16 does not cover their product. I cannot put it any more clearly  
17 than that.

18 THE COURT: Well, the only thing is is there some way  
19 that you can describe something about the products? What  
20 products -- I mean, what was the '250 patent?

21 MR. BLACK: The '250 patent was a -- the product  
22 itself is an opioid, a pain reliever. The '250 --

23 THE COURT: A pain reliever, OK.

24 MR. BLACK: The '250 patent covers products that have,  
25 as the base -- a product often has, almost always, has an

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1 active ingredient and some inactive ingredients. The inactive  
2 ingredients can be quite important in the context of a  
3 sustained-release drug that's going to go into and become  
4 active in the body for 12 or 24 hours. It is especially  
5 important with an opiate because you don't want to have a real  
6 spike in the drug; it could be extremely harmful.

7 The '250 patent had very specific claims that covered  
8 the use of in the excipient, the inactive ingredients, of locus  
9 bean gums, xanthan gum and five other ingredients -- three  
10 other ingredients. They had to be in very specific  
11 combinations and very specific percentages --

12 THE COURT: And their purpose was to do what?

13 MR. BLACK: The purpose was to enable the formulator  
14 to let the drug release into the body at a rate which would  
15 give pain relief but not spike so high that it would cause  
16 injury and that it would last for a lengthy period of time.

17 THE COURT: Just a minute.

18 (Pause)

19 Here's my note. '250 involved a pain reliever and  
20 there was something in that '250 patent which involved the  
21 release in such a way that there was no sudden spike, as you  
22 put it, and it would last for several hours. Have I put it  
23 down right?

24 MR. BLACK: Yes, your Honor.

25 THE COURT: All right. Now, that's the '250 patent.

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1 And I know that the defendants can speak for themselves, but  
2 just to save us time, what do you understand their -- what is  
3 the claim of that group about licensing?

4 MR. BLACK: The claim about not licensing, your Honor,  
5 if you look at -- so if you look at my chart on page 8 here, we  
6 all agree that the patents in the box on the top right, those  
7 things that are continuations of the '250 -- that is where  
8 things continue to happen in the Patent Office -- that's  
9 licensed. The patents at issue here are the '122 and the '216,  
10 which are not continuations of the '250. They are on the  
11 bottom right. Now --

12 THE COURT: And what are they?

13 MR. BLACK: They are relating to -- they are also  
14 relating to controlled-release pharmaceuticals, because that's  
15 what's at issue in the case, but the claim is completely  
16 different. It relates to placement of the composition in in  
17 vitro dissolution test and specific parameters for the test  
18 which demonstrates that at certain temperatures and that the  
19 oxymorphone, which is the active ingredient, is released from  
20 the tablet in the first claim in about one hour in the test.  
21 To infringe that claim you have to run a specific test and the  
22 product has to be within a particular parameters of  
23 dissolution.

24 THE COURT: What is oxymorphone?

25 MR. BLACK: Oxymorphone is very similar to Oxycontin.

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1 Oxycodone and oxymorphone are both very strong morphine-like  
2 substances.

3 THE COURT: Pain killers?

4 MR. BLACK: Pain killers. Very strong pain killers.  
5 They are Schedule II controlled substances.

6 What this case is about is we had originally had on  
7 the market our original oxymorphone product. We took it off  
8 the market and developed a new and improved product that is not  
9 as desirable to drug addicts, your Honor. It cannot be ground  
10 up and snorted the way the earlier version can. And we came  
11 out with this improved product, and that's why we're here, to  
12 protect the improved product.

13 THE COURT: And the improved product is --

14 MR. BLACK: It is also oxymorphone-based, but as I  
15 mentioned, there is the active ingredient and the excipient.

16 THE COURT: And what you are talking about now are the  
17 '122 and '216 patents?

18 MR. BLACK: Right, your Honor. The claims are very  
19 different from the '250, and the claims --

20 THE COURT: Before you get into that, but that's --  
21 did the '250 involve oxymorphone? Was it oxymorphone or for  
22 bean or what?

23 MR. BLACK: Oxymorphone, your Honor. Oxymorphone is  
24 actually a very old drug; it is off patent. The trick here is  
25 the extended release of oxymorphone for 12 or 24 hours. There

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1 are a lot of different ways to do that. And one way do it was  
2 the way we describe in the '250 patent, using locus bean gum  
3 and xanthan gum, which is not the way that the defendants used  
4 it and we therefor didn't sue them on it because it would have  
5 been a Rule 11 violation to do so. We all agree they didn't  
6 infringe that patent.

7 Another way to get this extended release is by using  
8 the inventions in the '122 and '216. It is a different way of  
9 going about it. The '250 was not infringed but these patents  
10 are.

11 Should I turn to the license, your Honor?

12 THE COURT: Well, the way you describe it, to the  
13 extent there was a license or an agreement not to sue, or  
14 whatever, it pertains solely to the '250 patent and  
15 continuation --

16 MR. BLACK: Precisely.

17 THE COURT: -- is that right?

18 MR. BLACK: Yes, your Honor.

19 THE COURT: And you're saying that -- and, obviously,  
20 they put out some products, the defendants. And you're simply  
21 saying that the patents that you are now suing on are very  
22 different from '250, right?

23 MR. BLACK: Right. And that they have never been  
24 licensed. They are so different that on the '250 we all agree  
25 they didn't infringe, and the on '122 and '216 they have not

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1 even contested infringement.

2 THE COURT: OK. Can we hear from the other side?

3 MR. WEISS: Thank you, your Honor. I will just  
4 introduce myself and then sit back down. Charles Weiss for  
5 Actavis.

6 There is one point that I want to clarify and  
7 Mr. Black may have misspoken. I think I know what he meant but  
8 it may not have really been clear. He said we are here to  
9 protect the improved product. That makes it sound as if the  
10 product that we are here about today is not the product that  
11 was settled and licensed in 2009. That is wrong. It is the  
12 same product, and the plaintiff concedes that it is the same  
13 product.

14 Now, plaintiff --

15 THE COURT: He hasn't conceded.

16 MR. WEISS: In their papers they do and in their  
17 complaint they do.

18 MR. BLACK: It is the same product, your Honor,  
19 different patents. The first batch were not infringed. This  
20 batch are infringed.

21 THE COURT: I don't understand what you are now  
22 saying.

23 MR. BLACK: The product that they're selling, your  
24 Honor, that was an issue in the last case is the same -- it is  
25 the same product they would like to sell now.

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1           The problem is we didn't have an opportunity to  
2           litigate the two patents that they do infringe because they  
3           hadn't been issued yet. They're trying to bootstrap our  
4           agreement not to sue them on the '250 patent, which we all  
5           agreed they did not infringe, into a defense in this case. And  
6           that's just wrong.

7           What was licensed were specific patents, not Endo's  
8           entire portfolio of patents.

9           THE COURT: Well, Mr. Weiss.

10          MR. WEISS: Thank you, your Honor.

11          So Endo does have a new product, which is protected by  
12          a whole bunch of other patents. There is a request to sell  
13          that new product pending at FDA by Actavis. That is a  
14          different lawsuit. It is in front of your Honor also. That is  
15          the new product.

16          The product that we're here today on, on this  
17          preliminary injunction application, is, as Mr. Black states  
18          correctly, it is the same product that was litigated in 2008  
19          and settled in 2009. So Endo is saying, although we granted  
20          you a license under the patents to begin selling in 2013, you  
21          can't do it. So they have two arguments -- or we have two  
22          arguments.

23          Now, the first one, which is what Mr. Black talked  
24          about, is whether the new patents would be called continuations  
25          of the old one. And I like his chart; I couldn't have done it

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1 better. So he has in blue the '357 application that was filed  
2 on July 6, 2001.

3 Your Honor can see that that application is --

4 THE COURT: I can't even read that through the color.

5 MR. WEISS: Well, I would apologize but it is not my  
6 chart. But in any event, it does say filed --

7 MR. BLACK: I apologize.

8 THE COURT: Is there writing in this dark -- I  
9 can't even see the writing.

10 MR. WEISS: There is, your Honor. Let me just read  
11 out the critical thing. The blue box on the left --

12 THE COURT: Why do people put writing in dark-colored  
13 boxes? I can never understand that.

14 MR. BLACK: I apologize, your Honor. We had some  
15 trouble reading it ourselves. I will endeavor to correct that.

16 MR. WEISS: So if I could, your Honor? So that is --  
17 I will just give the Court the key points in there.

18 That's application number '357, and it was filed on  
19 7/6/2001; July 6, '01. As the Court can see from the way the  
20 lines go, everything goes back to that application.

21 The family on the top, which is the '250 patent, where  
22 Endo has the red box that says "Patents Licensed," and the  
23 family on the bottom, where he says "Patents-in-Suit" that's  
24 green, they all go back to that application. And that  
25 application was filed three months before all the other ones on



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1 the left. Endo chose to claim priority to that application to  
2 get that date. With the benefit of that comes the burden of  
3 that, and these are continuations. They all go back to the  
4 same application.

5 THE COURT: You mean 7/6/01?

6 MR. WEISS: Yes. Well, that's the date, the one that  
7 was filed on 7/6/01, and the number is '357. It is the one in  
8 blue.

9 So, first of all, it is the same product.

10 Second of all, they are all related.

11 THE COURT: Here's what is going through my mind, and  
12 maybe if I state this it will simplify, maybe it won't.

13 Actavis and Roxane -- have I got the names right?

14 MR. CLEMENT: Yes, you do, your Honor.

15 THE COURT: OK. They have been putting out products  
16 and there was an earlier litigation, and somehow the '250  
17 patent of Endo was dealt with in some way in that litigation  
18 and it was agreed that the products of Roxane and Actavis did  
19 not infringe the '250 patent. And the products of Actavis and  
20 Roxane didn't then and they wouldn't now.

21 Now, what is going through my mind now -- it could be  
22 a great oversimplification so the lawyers should correct me,  
23 but it's my understanding, as I hear the discussion, that  
24 Actavis and Roxane are still making the same products. But  
25 Endo comes along with patents '122 and '216 -- new patents --

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1 and products that Actavis and Roxane had been making for some,  
2 whatever, number of years, all of a sudden there are some new  
3 patents obtained by Endo and Endo says the products you've been  
4 making all these years infringe the new patents.

5 Have I summarized things right or not?

6 MR. WEISS: Largely, your Honor. Let me just clarify  
7 one point.

8 THE COURT: OK.

9 MR. WEISS: When the Court said we've been making the  
10 products all these years --

11 THE COURT: When you are talking, about how many  
12 years?

13 MR. WEISS: So the settlement with Actavis was in  
14 2009.

15 THE COURT: OK.

16 MR. WEISS: And we've been on the market since 2011  
17 with two of the strengths.

18 So this product, like a lot of drugs, it has like  
19 5-milligram, 10-milligram, 20-milligram, there are different  
20 strengths. The settlement with Actavis allowed Actavis to go  
21 to market with two strengths in 2011, which it did, which it  
22 has been selling continuously, and allowed it to go to market  
23 in 2013 with respect to all of the other strengths.

24 So these are the same drug. It is the same approval.  
25 It is the same Abbreviated New Drug Application. It is the

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1 same formulation. But I don't want the Court to misunderstand  
2 that only two of the strengths have actually been on the market  
3 since 2011. The others, per the settlement agreement, could  
4 not be sold until 2013, which is why we're here in 2013.

5 MR. BLACK: I would like to clarify.

6 MR. CLEMENT: Your Honor, on behalf of Roxane, if I  
7 may?

8 THE COURT: Yes. Please. You are?

9 MR. CLEMENT: Mr. Clement, Alan Clement.

10 THE COURT: All right.

11 MR. CLEMENT: So somewhat similar to Actavis, Roxane  
12 actually has not been selling any product. We had this earlier  
13 lawsuit based on an ANDA that Roxane filed back in 2010. Endo  
14 looked at that ANDA, and it fully describes the product that  
15 Roxane would sell today if they could.

16 THE COURT: Looked at what?

17 MR. CLEMENT: They looked at our ANDA; it is an  
18 Abbreviated New Drug Application. It completely describes  
19 every little nuance of the product that the party, that the  
20 generic company, is trying to -- is seeking approval from the  
21 FDA. Before you can sell a product, a prescription drug  
22 product, you need approval from the FDA. So you need to clear  
23 FDA hurdles and you also need to clear patent hurdles.

24 So in 2010 we filed our drug application, and we have  
25 to describe everything about it -- what it is made of, how it

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1 dissolves, how it acts on the body, all of these things -- to  
2 the FDA. That information was given also to Endo in that suit.  
3 That's what caused the first suit, which also involved the '250  
4 patent and a couple of other patents.

5 During that lawsuit it was agreed to settle that  
6 lawsuit. They knew what our product was. If Roxane was ever  
7 going to sell the product, they knew what it was. They decided  
8 to settle that litigation as to all the patents Endo had at  
9 that time. They said once certain other parameters are met,  
10 other parties' exclusivities, then Roxane would be entitled to  
11 enter the market.

12 Roxane has now obtained its approval from the FDA, all  
13 those other exclusivities have expired, and Roxane should be  
14 entitled to sell the product described in that very same ANDA,  
15 Abbreviated New Drug Application, that Endo previously agreed  
16 in settlement of a lawsuit to license, Roxane should be  
17 entitled to go to market with that product.

18 MR. BLACK: If I might --

19 THE COURT: Let me just follow up with what I think I  
20 would like to follow up with for the moment.

21 Now, I think, the status of what Mr. Weiss and  
22 Mr. Clement have described, I'll assume they've described  
23 things correctly as far as they go.

24 Now, the new elements that come in, you've got these  
25 products that either were being sold or being described as

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1 Mr. Clement says and being submitted for approval and so forth.  
2 OK. All of which is kind of a machinery that's going on  
3 beginning 2009 or thereabout, whatever.

4 Now, so all of this is set up. It's been agreed to.  
5 The products are either being sold or their permission is being  
6 obtained to sell them and so forth.

7 Now, along comes Endo with two new patents and says  
8 all these things that you have been selling or been seeking  
9 approval of violate the new patents.

10 Isn't that the situation?

11 MR. WEISS: Yes, your Honor.

12 MR. BLACK: In part, correct, your Honor. Largely  
13 correct.

14 THE COURT: I mean, just sitting here as a judge, and  
15 almost as a layman, that sounds so terribly unfair. It sounds  
16 terrible.

17 You make these agreements. These agreements are acted  
18 on. And then you file a couple of new patents, and you say all  
19 these things you agreed to let them do infringe the new  
20 patents.

21 MR. BLACK: Your Honor --

22 THE COURT: I mean, that just sounds like -- is this  
23 America or not? It sounds terrible.

24 MR. BLACK: Your Honor, this is not, as you said, in  
25 some ways you are a layman on this. These defendants knew

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1 exactly what was happening. These applications were published  
2 and known. There were explicit negotiations with Roxane where  
3 Mr. Donatiello, from Endo, sitting in the back of the room,  
4 told the negotiator for Roxane that they were not going to get  
5 rights to these patent applications, and if these patents ever  
6 issued we would have a dispute that would have to be resolved.  
7 They have not launched these products yet that are at issue in  
8 the preliminary injunction. Our purpose is to try to maintain  
9 the status quo until we can have our patent claim adjudicated.  
10 We can't bring a patent claim until the Patent Office issues  
11 the patent, which didn't happen until late last year.

12 THE COURT: You know, you're really not saying  
13 anything that is very helpful to me.

14 I mean --

15 MR. BLACK: Your Honor, would it be helpful if it were  
16 proved, as I think it is, that Roxane was aware at the time  
17 that it entered into the agreement that these patents could  
18 issue and that they agreed with Endo not to take a license,  
19 that they were not getting a license on these patents; that  
20 this was known to the parties and it was part of the agreement?

21 THE COURT: Then it seems to me that Actavis and  
22 Roxane were doing an awful lot of wheel spinning.

23 MR. BLACK: Nobody knew for sure whether these patents  
24 were going to issue.

25 THE COURT: Which patents?

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1 MR. BLACK: The two, the '122 and the '216 patent were  
2 in the Patent Office at the time that the prior case was  
3 settled. The Patent Office may never have issued the patents;  
4 the Patent Office may have issued it. As it happened, these  
5 patents went up to the Federal Circuit before they were issued,  
6 and now the Federal Circuit told the Patent Office that they  
7 needed to issue them.

8 But none of that happens and the patents didn't issue  
9 until late last year. And we brought the case before they've  
10 come to market with the dosage strengths that are at issue and  
11 said, hey, we got a patent claim now. If we had this claim  
12 five years ago, we would have brought it but we didn't have it  
13 because those patents were still being reviewed by the Patent  
14 Office and the Federal Circuit. But now we have a claim. We  
15 have a constitutional claim. We have a claim to assert these  
16 patents. It is a property right. And all we're asking at this  
17 point is that that property right is adjudicated before they  
18 launch and disrupt the market. And that's what we're here for.

19 MR. CLEMENT: Your Honor, for Roxane, if I may for  
20 Roxane?

21 I think that what Mr. Black is saying is absolutely  
22 contrary to the language in the agreement with Roxane. The  
23 Roxane agreement defines the licensed patents as any United  
24 States patent applications -- and you can read this from slide  
25 6 of Endo's slide package -- any United States patent

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1 applications that claim priority to the Opana ER Patents,  
2 including any continuations, continuations-in-part and  
3 divisionals.

4 OK. So it's not limited to continuations,  
5 continuations-in-part or divisionals, as Mr. Black would like  
6 you to believe.

7 It also has this language, that the parties agreed to  
8 that is in the agreement, that says that it includes any patent  
9 applications that claim priority to the Opana ER patents.

10 And if you go back to Mr. Black's chart, which is on  
11 page 8, you can see that the green blocks claim priority back  
12 to the blue block, which is a priority claim to the '250  
13 patent. So it is within the explicit language of the agreement  
14 as written.

15 THE COURT: Well, I have to confess to you, I don't  
16 understand what you're saying. I'm trying to.

17 MR. CLEMENT: All right.

18 THE COURT: I don't quite understand it. Go over this  
19 again.

20 MR. CLEMENT: Sure. OK. Can I give you my slide  
21 pack? Can I approach?

22 THE COURT: Of course.

23 (Handing to the Court)

24 MR. CLEMENT: Your Honor, if you would look at slide 6  
25 first. This is just to show that there is a settlement



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1 agreement and license between Endo and Roxane.

2 Are you with me?

3 THE COURT: All right. Let me find 6.

4 MR. CLEMENT: OK.

5 THE COURT: OK. I've got 6.

6 MR. CLEMENT: So 6 is just a cover page to show that  
7 there was a settlement agreement of that earlier lawsuit that  
8 we had spoken about.

9 If you turn the page, all right, that presents to you  
10 Section 4.1 of the Agreement, which sets forth what is the  
11 license that is granted. And the license is from Endo to  
12 Penwest -- Endo and Penwest hereby grant to Roxane a  
13 nonexclusive, nontransferable, nonsublicenseble, royalty-free  
14 license under something known as the licensed patents. OK. So  
15 they are granting a license under the licensed patents so that  
16 Roxane can make, use, or sell the Roxane products.

17 OK? That's what the licensed patents --

18 THE COURT: Wait a minute.

19 (Pause)

20 OK, go ahead.

21 MR. CLEMENT: Now we have to understand what are these  
22 licensed patents. That becomes the question. Roxane has a  
23 license under the licensed patent. If you flipped two pages --

24 THE COURT: Wait a minute. Where is the --

25 MR. CLEMENT: About seven lines down, "Under the

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1 Licensed Patents, during the licensed" --

2 THE COURT: One, two, three, four -- under the  
3 "Licensed" --

4 MR. CLEMENT: "Patents."

5 MR. BLACK: Your Honor, if you look at our slide 3, it  
6 has the same information but ties it together with some arrows,  
7 too.

8 THE COURT: OK. Go ahead, Mr. Clement.

9 MR. CLEMENT: So if we go two more pages in the slide  
10 book to page 9, that is where "licensed patents" are defined in  
11 the Endo/Roxane License Agreement.

12 And you can see from that language there are three  
13 different types -- three different groups of patents that are  
14 licensed. A is "Any United States patent that was now owned by  
15 Endo and issued as of the effective date of this agreement."  
16 All right. That's not what we're talking about here today.  
17 OK?

18 B -- this is what we are here talking about -- "Any  
19 United States patent applications that claim priority to the  
20 Opana ER patents." And then it goes on, it says, "including,"  
21 which means -- which is a broad term which means it includes  
22 these but it can also include other things. "Including any  
23 continuation, continuation-in-part, and divisional applications  
24 that claim priority to the Opana ER patents."

25 And it goes on in each case that Endo or Penwest could

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1 assert, would be infringed by the making, using, or selling of  
2 the Roxane product.

3 So the key language here, your Honor, is that first  
4 phrase. It says, "Any United States patent applications that  
5 claim priority to the Opana ER patents." OK? And what has  
6 happened here, your Honor, is the two patents that are being  
7 currently asserted against Roxane, the '122 and the '216, they  
8 claim priority to the Opana ER patents precisely as --

9 THE COURT: What is the Opana ER patents?

10 MR. CLEMENT: OK. The next slide, your Honor, tells  
11 you what the Opana ER patents are. I'm sorry, I should have  
12 directed your attention to this. But it is the three patents,  
13 the '933, the '456 and the '250. The '250 being key.

14 THE COURT: Go back to the language on page 9.

15 MR. CLEMENT: All right. 9 says claim priority to  
16 those patents, to any one of those three patents. What we're  
17 saying, what Roxane says, is that claim priority to the Opana  
18 ER patents includes claims priority to the '250 patent. And  
19 precisely as shown in Endo's chart with the blue and the green  
20 and the yellow charts, it goes back and shows this claim to  
21 priority.

22 And we can see that, your Honor, in our slides, as  
23 well. If you turn to slide 13 --

24 THE COURT: I am really am -- I'm not taking in, as I  
25 would like to, what is being presented here. Is there any way

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1 you can simplify it or --

2 MR. CLEMENT: Sure. What I'm saying, your Honor,  
3 is --

4 THE COURT: -- or summarize it? I will be very frank  
5 with you; I'm just not taking it in.

6 MR. CLEMENT: I think, your Honor, what I'm trying to  
7 say here is that these '122 and '216 patents were contemplated  
8 by the Agreement as written, by this language claims priority  
9 to, because, as Endo has shown, there is a common linkage  
10 between all these patents, that the '122 and the '216 were  
11 licensed at the same time the '250, the -- all of the Opana ER  
12 patents. That is what I am trying to say as simply as  
13 possible.

14 THE COURT: Well, I can understand that.

15 MR. CLEMENT: And, your Honor, there was a reason for  
16 Endo wanting to claim priority to these patents. If I may  
17 continue?

18 THE COURT: Well, what is the significance of claiming  
19 priority?

20 MR. CLEMENT: Claiming priority means you needed it to  
21 rely on to file your new application. There is information in  
22 an old application that you needed to rely on to make your new  
23 claim.

24 And if I could show you, your Honor, actually? If you  
25 turn to slide 17? Slide 17 discloses -- shows where the

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1 dissolution profiles, how these patents all tie together.

2 OK. What I have in the upper left-hand corner is  
3 what's in the blue box in Endo's diagram. That's that '357  
4 provisional filed on 7/6/01. OK? And in that -- this is what  
5 this is all about, your Honor. There they had some examples of  
6 formulations that would have certain amounts of oxymorphone  
7 released in a beaker over a certain time period as it  
8 dissolves. OK? And what happens is they carried that same  
9 profile into the '250 patent. It's Table 4 in the '250 Patent,  
10 and it's also in the two new patents Endo is trying to assert,  
11 the '122 and the '216. They need --

12 THE COURT: What do you mean -- when you say something  
13 is also in '122 and '216, what is it that is in there that is  
14 significant?

15 MR. CLEMENT: OK. So the table -- what the '122 and  
16 the '216, the claims that are being asserted against Roxane,  
17 those claims talk about how much is dissolved in a certain  
18 period of time no matter what formulation you use. OK? And  
19 what they had in the '357 patent, at pages 9 to 10, is a table.  
20 And they made compositions and they put them in a beaker and  
21 they watched them dissolve and they calculated how much  
22 dissolved over a period of time. That information was the  
23 basis for what they later claim in the '122 and the '216  
24 patents. So that same table that was in the blue box  
25 application appears in the green box patents, the '122 and the

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1 '216.

2 And if you'll take a look -- if you'll bear with me  
3 one more second, your Honor. If you'll take a look at the next  
4 page. I know I'm going a little --

5 THE COURT: Page what?

6 MR. CLEMENT: Page 18. These are the claims that Endo  
7 is asserting.

8 So you'll see Claim 1 of the '122 patent has a bunch  
9 of information about that they want to have a controlled  
10 release pharmaceutical composition. But what they're really  
11 claiming is that -- at the last couple of lines of that first  
12 claim -- about 15 percent to about 50 percent by weight of  
13 oxymorphone is released from the tablet at about one hour in  
14 the test.

15 Do you see that?

16 THE COURT: I do. What is the significance of that?

17 MR. CLEMENT: Because if you go back to the table that  
18 I was just showing you and you look at the time points, you  
19 will see that this is the support for what they tried to claim  
20 in the '122 and the '216. At the one-hour time point in the  
21 '357 application, they released 27.8 percent and 32.3, which is  
22 smack in the middle of 15 to 50. That's why they carried this  
23 through to the '122. At the one-hour time point it is the  
24 same, 27.8 and 32.3. It is the same example. It is going to  
25 be the same thing for the '250, 27.8 and 32.3. It is the exact

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1 same example.

2 So they needed this as the basis for their claim to  
3 priority, which is the same language that is in the settlement  
4 agreement claim to priority. So there is a direct license,  
5 your Honor, between the license agreement that Endo and Roxane  
6 entered into and also what is in these patents, these later  
7 patents that all of a sudden, as Endo would like you to  
8 believe, issued out of thin air. No, they were based on old  
9 things that were also in the '250 patent and applications  
10 claiming priority to the '250 patent.

11 If you look at Claim 2 of the '122 patent, there it  
12 talks about 45 to 80 percent release at four hours. We can do  
13 the same thing. In the '357, it is 58 and 66. The '250  
14 patent, 58 and 66. The '122, 58 and 66. The '216, 58 and 66.  
15 Again, smack-dab in the middle of what they're trying to claim  
16 now.

17 The same thing for Claim Three; at least about  
18 80 percent at 10 hours. We can go to the 10-hour number, 85  
19 and 90, again, meeting the limitations. They needed this.  
20 They claimed priority to it. Roxane specifically covered this  
21 in its agreement with Endo.

22 So it's not just this form, you know, continuation  
23 that's up there in cyberspace or whatever and has no meaning.  
24 This has real meaning, your Honor. There is substance to this;  
25 it is not just form. They claim priority back to the '250

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1 patent because if they didn't they would not have been allowed  
2 to get their '122 and '216 patents issued.

3 THE COURT: What about that last statement, Mr. Black?

4 MR. BLACK: There is a lot of hand waving going on  
5 here, your Honor.

6 This issue about which patents were going to be  
7 included within the license and which were not going to be  
8 included was specifically discussed between the parties. We  
9 have a declaration from Mr. Donatiello stating that he  
10 discussed this issue with Mr. Dow, of Roxane. We have a  
11 negotiating history that I would like to refer to in a moment,  
12 and that Roxane knew this was an issue and agreed not to get a  
13 license to these applications.

14 For him to say that -- by showing a couple of tables  
15 next to each other that they somehow got a license, that  
16 doesn't change the scope of the Agreement or what the parties  
17 were negotiating. It's completely irrelevant.

18 What is relevant is the analysis he started down the  
19 road of, which is looking at the license, looking at the  
20 definition of licensed patents, and looking to determine  
21 whether or not these new patents are covered by that  
22 definition. The answer is they are not.

23 THE COURT: Why are they not?

24 MR. BLACK: If you would look at page 3 of our  
25 presentation, your Honor, this presents most of the same



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1 information that Mr. Clement was discussing a moment ago.  
2 We've just tried to put it on one page, and hopefully the  
3 arrows will help illuminate rather than confuse.

4 But there is a license under -- this is Section 4.1,  
5 under the "Licensed Patents." Contract construction. What are  
6 the licensed patents? It covers several categories, including  
7 B, "Any United States patent applications that claim priority  
8 to the Opana ER patents." That is the key phrase, "priority to  
9 the Opana ER patents."

10 THE COURT: Just a minute.

11 (Pause)

12 Go over the language you were referring to, Mr. Black,  
13 again.

14 MR. BLACK: Sure, your Honor. The agreement is under  
15 the "Licensed Patents." The licensed patents are defined in  
16 1.16, which is the second section there on the page, and what's  
17 licensed is patent applications that claim priority to the  
18 Opana ER patents.

19 So you have to ask, OK, we'll get to the question of  
20 what claiming priority means in a moment, but just so we have  
21 everything fixed. Claim priority to the Opana ER patents, so  
22 it's claim priority to Opana ER patents, as defined. And  
23 there's our magical '250 again. Do you see the '250 patent?

24 THE COURT: Right.

25 MR. BLACK: So they have to show, in order to prevail

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1 under a license defense, that the patents at issue today claim  
2 priority to the '250. Claim priority to the '250 because  
3 that's what are the Opana ER patents.

4 And what I was saying a moment ago, your Honor, is  
5 that this was an explicitly negotiated provision. It would  
6 have been very easy for the parties to write an agreement that  
7 said you have a license to all of Endo's patents. They didn't  
8 do that. They gave a license to certain patents only. And the  
9 only way they can prevail is if they could show that the  
10 patents-in-suit now claim priority to the '250, and they can't  
11 do that.

12 Now, for him to say that the Agreement is broader --

13 THE COURT: Why can't they do that?

14 MR. BLACK: They can't do that because if your Honor  
15 will take a look at the page 7, this is the face of the patent.  
16 And this is a crucial point, your Honor, which is that there is  
17 no uncertainty about which patents are continuations or which  
18 patents claim priority to the '250, because the priority  
19 information and the continuation information is printed on the  
20 face of every patent.

21 So on page 7 we have a cutout of the '122. I'm sorry,  
22 even with the blowup, the writing is a little bit small. But  
23 what it says is that the '122 is a continuation of Application  
24 10/190,192. It doesn't say that this '122 patent is a  
25 continuation of the '250. It doesn't say that. It is not a

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1 continuation of the '250. Therefore, they cannot demonstrate  
2 that a claims priority --

3 THE COURT: It doesn't say it is a continuation. Do  
4 they?

5 MR. CLEMENT: No, we don't, your Honor.

6 MR. BLACK: That is right.

7 MR. CLEMENT: We make a claim of common priority.

8 MR. BLACK: Common priority. So the next point, your  
9 Honor, is that it also says what it claims priority to, and it  
10 claims priority to four provisional applications, which are  
11 special types of applications that can be filed, which are not  
12 complete and don't have to be prosecuted, but the four  
13 provisional applications that are referred to are also stated  
14 on the face of the patent. None of those is the '250 patent.

15 THE COURT: Where are they listed?

16 MR. BLACK: That's just below the common application.  
17 It might be better to look on the right.

18 THE COURT: I'm looking at the right.

19 MR. BLACK: OK. I'm sorry. I was looking at the left  
20 side.

21 This application is a continuation of U.S. patent  
22 Application Serial Number '192 and claims priority to U.S.  
23 provisional applications, and then it gives four numbers. It  
24 doesn't say the '250 patent. And the reason it doesn't say it  
25 is because that provision was explicitly negotiated by the

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1 parties at the time this agreement was entered into, your  
2 Honor.

3 This is not a surprise to Roxane. I represented to  
4 the Court several times that it was negotiated by the parties,  
5 and they gave up that right and they only got a license to  
6 limited patents. And there was a discussion with Mr. Dow, and  
7 the materials are in our package. And he hasn't denied it  
8 because it was true. That was the deal.

9 THE COURT: Do we have those things up here in court?

10 MR. BLACK: What?

11 THE LAW CLERK: Which declaration?

12 MR. BLACK: The declaration of Mr. Donatiello.

13 Yes, it would be paragraph 39.

14 THE LAW CLERK: Of which one?

15 MR. BLACK: Let me see.

16 (Pause)

17 39.

18 (Handing to the law clerk)

19 MR. BLACK: So in paragraphs 38 and 39, your Honor --  
20 I'll just let you review those.

21 MR. CLEMENT: Your Honor, just for the record. This  
22 is parol evidence and I believe it is also hearsay.

23 (Pause)

24 THE COURT: Who is Mr. Dow?

25 MR. BLACK: Mr. Dow was the negotiator for Roxane,

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1 your Honor.

2 THE COURT: And this declaration is by?

3 MR. BLACK: Mr. Donatiello, the negotiator for Endo.

4 And it is uncontested, undisputed.

5 MR. CLEMENT: It was just served on us Tuesday.

6 Mr. Dow is in Germany and has not had a chance to respond.

7 THE COURT: How about Actavis?

8 MR. BLACK: Actavis doesn't have this common priority  
9 language. There is no ambiguity about their Agreement in any  
10 way, shape or form.

11 Their Agreement is on page 2 of our presentation, the  
12 relevant provision, and they have only continuations to the  
13 '250. And it is undisputed that the patents-in-suit are not  
14 continuations of the '250.

15 THE COURT: What do you say, Mr. Weiss?

16 MR. WEISS: Well, a few points, your Honor.

17 First, Endo spoke a lot about the parties, the  
18 parties, the parties. But this evidence of the alleged  
19 discussions between Endo and Roxane goes only to Roxane. That  
20 occurred in 2011. The Actavis license was granted in 2009.  
21 And there is no similar information about alleged agreements  
22 between Endo and my client. So I have no idea what the effect  
23 is as to Roxane, but there is no similar evidence as to  
24 Actavis.

25 As to the second point, continuation or common

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1 priority, Mr. Black said it is uncontested. It is not  
2 uncontested.

3 And if we could look back briefly? This is at his  
4 slide 7. He pointed out -- and the language is what it is  
5 here. It is a continuation of this patent application  
6 10/190 --

7 THE COURT: That is page 7?

8 MR. WEISS: Yes. This is page 7 of Endo's slides.

9 THE COURT: Go ahead.

10 MR. WEISS: OK. And then it says "and claims priority  
11 to," and then it lists the applications it claims priority to,  
12 which include the application --

13 THE COURT: Where are you reading now?

14 MR. WEISS: I'm in the yellow here. So do you see  
15 where he has underlined "and claims priority to"?

16 THE COURT: I see that.

17 MR. WEISS: OK. And then it says, "U.S. Provisional  
18 Patent Application Serial Nos. 60/329,445, filed October 15,  
19 2001; 60/329,432, filed October 15, 2001," and then here's the  
20 key one, "60/303,357, filed July 6" --

21 THE COURT: Wait a minute.

22 (Pause)

23 I guess I'm not with you in where I'm reading.

24 MR. WEISS: Can I --

25 THE COURT: Is this page 7 of Endo's --

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1 MR. WEISS: Slides.

2 THE COURT: And it is in the right-hand box?

3 MR. WEISS: Correct. He has the blowup.

4 THE COURT: And where do you see '357?

5 MR. WEISS: OK. It is three lines up from the bottom,  
6 in the highlighted portion. '357 filed July 6, 2001.

7 THE COURT: Bring me up what you are talking about  
8 because I just don't see it.

9 (Pause)

10 MR. WEISS: It is right here, your Honor.

11 (Indicating)

12 THE COURT: Oh, I've got a different page. Oh, no, I  
13 don't. Thank you very much.

14 MR. WEISS: Thank you.

15 THE COURT: Now, I didn't see the '357. What is the  
16 significance of that?

17 MR. WEISS: So that, your Honor, is the ultimate  
18 priority application. This is the one that was in the blue box  
19 that was hard to read on page 8 of Endo's slide deck.

20 THE COURT: I just can't read those boxes.

21 MR. WEISS: Right. But that is the '357 application.

22 So that is the --

23 THE COURT: On the far left?

24 MR. WEISS: Correct. That is the ultimate parent with  
25 the earliest date and, as Mr. Clement pointed out, is the

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1 source of the tables and the examples that have the dissolution  
2 data that ultimately support the claims at issue here in the  
3 new patents.

4 THE COURT: What does that material on page 7 of  
5 Endo's material, what does it have to do with the license  
6 issue?

7 MR. WEISS: Right. So -- well, there are two  
8 different license claims and we've only talked about one. But  
9 there is the claim -- and this is a common claim by both Roxane  
10 and Endo -- that there is an express license to the '122 patent  
11 and the '216 patent. These are the new patents that issued in  
12 2012 that we are here on today. And the basis is --

13 THE COURT: Who claims that?

14 MR. BLACK: I think you meant Actavis.

15 MR. WEISS: I'm sorry. I misspoke. Thank you. Sorry  
16 about that.

17 Both defendants have an express license claim that the  
18 settlement of the earlier case, and the definition of the Opana  
19 ER patents, expressly includes the patents we're here on today,  
20 '122 and '216, by virtue of the common priority claim through  
21 and back to the '357 application filed in July 2001. It has  
22 the exact dissolution data that the current claims depend on.

23 But I would like to raise the other point which we've  
24 not spoken about yet today. This goes back to your Honor's  
25 observation where you said that sounds terrible, that you



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1 litigated the earlier case, you settled, here we are again on  
2 the same product. This is the estoppel -- the license by  
3 estoppel issue.

4 The facts of this case, where there is settlement of  
5 litigation and then a second lawsuit on new patents, are not  
6 unique and is not uncommon. So we discuss in some detail in  
7 our brief a Federal Circuit case from 2009 -- and this is the  
8 Transcore case. It is Transcore v. Electronic Transaction  
9 Consultants, 563 F.3d 1271, and I spoke about this case when we  
10 were in front of your Honor the last time. Very similar  
11 situation.

12 Settlement of an earlier lawsuit. A new patent  
13 issues, and the patent owner is back at it again. And the  
14 patent owner argued in that case, like Endo argues here, that  
15 there is language that says, in the settlement agreement, this  
16 doesn't apply to other patents. The Federal Circuit says that  
17 doesn't do it. You are estopped because that deprives the  
18 licensee of the benefit of its bargain. The subject matter  
19 that you licensed to settle in the earlier case did not  
20 survive.

21 And, again, that is not a new doctrine. This is not  
22 uncommon estoppel law. It comes up time and again.

23 There is another case, which is discussed and cited in  
24 Transcore, from 1968, from the Court of Claims. And this is  
25 when the Court of Claims heard all their cases en banc. So

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1 this is counsel's binding Federal Circuit precedent, by the  
2 way. And the citation to this, this is AMP v. United States,  
3 389 F.2d 448 (Court of Claims 1968). The same type of  
4 situation. There is a license agreement between a contractor  
5 and the federal government on -- what turns out, they refer to  
6 the patents there by name -- the Byrem patent. That was the  
7 man, the employee of the contractor.

8 After that is done, the contractor finds that somebody  
9 else, another company, owns another patent that actually  
10 dominates the Byrem patent. And that is referred to in the  
11 case as the Vinson patent, V-i-n-s-o-n. They buy the patent.  
12 They didn't own it at the time. They buy the patent. They sue  
13 the federal government for patent infringement in the Court of  
14 Claims.

15 The federal government says we're licensed by  
16 estoppel. But one of the defenses there was, but this Vinson  
17 patent we didn't even own at the time, and if we had not bought  
18 it you would have no defense, if it was in the hands of a third  
19 party. And the federal government says, yeah, that's right,  
20 but you did buy it, and you deprive us of the benefit of the  
21 bargain.

22 The Court makes a point there that I think is  
23 important to point out. The pen cite is page 452. So it is  
24 389 F.2d at 452. And it talks about that the estoppel here is  
25 not what it refers to as estoppel in pais; it does not require

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1 any kind of false representation or trickery or misleading  
2 action.

3 Now, what was in Endo's head in 2009, when it settled  
4 with Actavis, I don't know, and I don't really care. What was  
5 in Endo's head, its unexpressed intent to Actavis would be  
6 irrelevant anyway. So we don't have to prove bad faith or  
7 trickery or anything like that.

8 But, again, the AMP v. United States case says you  
9 grant a license. You get a new patent that covers the same  
10 thing. You can not enforce it.

11 THE COURT: You what?

12 MR. WEISS: Can not enforce it on the exact subject  
13 matter that you licensed. This is not a new doctrine.

14 There is another case --

15 THE COURT: You know, you can't, c-a-n-n-o-t?

16 MR. WEISS: Can not, yes.

17 There is another case --

18 THE COURT: All right. Now, look, we've got to  
19 take -- let's take a short break and then come back and I've  
20 got to make some rulings. All right?

21 MR. WEISS: Thank you, your Honor.

22 (Recess)

23 THE COURT: We have before the Court a motion for a  
24 preliminary injunction by Endo against Actavis and Roxane, and  
25 Endo seeks a preliminary injunction on the basis of Patents

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1 '122 and '216. Now --

2 MR. BLACK: And '482 with respect to Actavis, your  
3 Honor. I'm sorry to interrupt but there is a third patent.

4 THE COURT: OK. We've had a hearing this morning  
5 relating to an issue which I thought was pivotal and I still  
6 think is pivotal, and that is the question of whether because  
7 of licenses or because of circumstances connected with  
8 licenses, at least for preliminary injunction purposes, whether  
9 Endo can succeed in obtaining a preliminary injunction in view  
10 of these license issues.

11 I'm ruling that the preliminary injunction must be  
12 denied.

13 Now, I will not adjourn to write a detailed decision.  
14 The record is full of the facts that are essential here -- the  
15 earlier litigation, the settlement of the earlier litigation,  
16 and so forth -- and the details of that I will not try to  
17 recite in a bench ruling, because they are well known and they  
18 are in the record without having to be repeated by me at this  
19 moment.

20 But there was the earlier litigation, and there was a  
21 settlement. And an important part of that settlement was a  
22 recognition that a patent with the number '250 was not  
23 infringed. But the parties did not simply leave that in that  
24 posture. There were agreements made which specifically  
25 recognized that the products of Actavis and Roxane were not

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1 infringing, and those products would be permitted.

2 The status of the products is not simple. There were  
3 certain products by Actavis either on the market or about to go  
4 on the market.

5 As far as Roxane, the effort has been to obtain FDA  
6 approval, but that has been a very substantial effort, with a  
7 view towards putting a product or products on the market.

8 So what emerged from that settlement, or that earlier  
9 litigation, was clearly the right of Actavis and Roxane to  
10 pursue the permitting process and the marketing process with  
11 respect to the products which all parties understood they were  
12 engaged in either marketing or getting permits for.

13 And I emphasize that that settlement led to a  
14 substantial effort on the part of Actavis and Roxane in  
15 response to that settlement, and the licenses, which were the  
16 effect of that settlement.

17 Now, the basis of Endo's claim now is that there are  
18 two new patents -- are there three?

19 MR. BLACK: There are three, your Honor. One is  
20 completely unrelated to any of the others.

21 THE COURT: Well, the number of the third is what?

22 MR. BLACK: '482.

23 THE COURT: So I need to refer to '482, right, as well  
24 as to '122 and '216? Well, if I do, I do. It is '482?

25 The discussion here this morning has been involved

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1 with '122 and '216, and I'm not claiming to be greatly informed  
2 about '482. But I assume that, on the licensing issue, it  
3 stands along with '122 and '216.

4 MR. BLACK: It does not, your Honor.

5 THE COURT: What?

6 MR. BLACK: It really does not.

7 THE COURT: What, do we have to have another hearing  
8 about '482?

9 MR. BLACK: No, your Honor. I understand where you  
10 are going. I just didn't want to -- I just wanted to make --  
11 '482 is not in the same family as the '122 and the '216. It is  
12 acquired from another company.

13 THE COURT: Well, if you want to adjourn for another  
14 hearing about '482, make your application now. Do you want to  
15 adjourn for that?

16 MR. CLEMENT: Your Honor, they've already said it is  
17 not asserted against Roxane.

18 MR. BLACK: That is true; it is not asserted against  
19 Roxane, only against Actavis.

20 THE COURT: Look, the discussion this morning, a very  
21 substantial discussion, has been exclusively concerned with  
22 '122 and '216, and I am going to talk about '122 and '216, and  
23 to the extent that there is any implication needed for '482,  
24 the parties can draw that. But there has been no discussion  
25 before me about '482, and I'm not going to discuss it now.

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1 Let me go ahead.

2 There were two -- and I'm going to refer to two new  
3 patents and that's what I'll refer to, because that's what's  
4 been discussed all day.

5 MR. BLACK: We did refer to the '482, and we've moved  
6 for preliminary injunctive relief on the '482 against Actavis.

7 THE COURT: I'll come to that, but my discussion now  
8 is going to be about what has been discussed here this morning,  
9 very extensively in open court, and that's about '122 and '216.  
10 But these are new patents, and the claim is that the products  
11 that Actavis and Roxane are either marketing or seeking  
12 permission for these products infringe '122 and '216. And the  
13 request for a preliminary injunction is on the basis of that  
14 claim of infringement.

15 Now, a great deal of time was spent today on the  
16 detailed language of one or more agreements entered into at the  
17 time of the earlier litigation and the references to patents  
18 and the details of certain patents said to be referred to in  
19 those agreements. And one side claims that applying that  
20 language to what is known about certain patents, Endo claims  
21 that that shows that there was no intent to license or give any  
22 permission to market products or seek permission of anything  
23 that would infringe '122 and '216.

24 The other side claims that if you examine the  
25 agreements in the earlier litigation, the agreement language,

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1 and you analyze it carefully in view of what is known about  
2 certain patents, that it will show that there was no intent to  
3 project any possibility of litigating infringement about '122  
4 and '216, and then, indeed, the licenses and permissions are  
5 broad enough to cover '122 and '216.

6 I wish to say for the record that I do not feel, for  
7 purposes of a preliminary injunction motion, that I am able to  
8 make any findings on the issues that I have just described, and  
9 I want to make it clear that that's exactly where I stand. I'm  
10 not saying that the plaintiff has not sustained its burden of  
11 proof, and I'm not saying that the defense has not sustained  
12 whatever burden they need to sustain. I am simply not able to  
13 make any findings on the issues which I have just described.  
14 Probably my description is not artful, but I think the lawyers  
15 here know exactly what I'm talking about. In my view, a much  
16 more substantial hearing and, indeed, a full trial would be  
17 necessary to fully explore what is involved in the issues I am  
18 talking about now.

19 What is clear, however, to me is this. That an  
20 agreement was made, and whether it's called a license agreement  
21 or an agreement not to sue I won't worry about for the moment.  
22 We'll call it a license agreement because that's how things  
23 have been described by the lawyers today. We're talking about  
24 licenses.

25 And what is clear is that those licenses, or that



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1 license, gave permission to Actavis and Roxane to go forward  
2 with marketing the products and seeking permission for the  
3 marketing of the products that have been the subject of their  
4 activity since the time of the litigation up to and including  
5 the present moment.

6 There is a doctrine bearing the name estoppel, and  
7 there's case law about the problem we have here. And that is  
8 where a license is given, or permission is given, or where for  
9 any other reason it is legal for a company to market a product  
10 and such marketing is done and then another company comes in  
11 with new patents and says you infringe my new patents, under  
12 the circumstances that we have here, which may be different  
13 from other circumstances, but under the circumstances that we  
14 have here that is a highly unfair and unjust situation if that  
15 were to be -- if infringement of the new patents would stop the  
16 marketing and permitting process that was going on by Actavis  
17 and Roxane.

18 Consequently, I am holding as a matter of law and I'm  
19 finding that Endo is estopped from claiming that the activity  
20 of Actavis and Roxane, which has gone on for a substantial  
21 period of time, is now suddenly barred because of these new  
22 patents. For those reasons, the motion for a preliminary  
23 injunction is denied.

24 And I will submit -- I will sign an appropriate order  
25 prepared on notice. Thank you very much.

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1 MR. BLACK: Your Honor, one last thing. I'm sorry.

2 THE COURT: OK.

3 MR. BLACK: I understand the ruling and the question  
4 is where do we go from here? We ask for leave to have seven  
5 days to file an emergency appeal with the Federal Circuit and  
6 let the status quo be maintained in the interim either by  
7 agreement with the defendants or, if necessary, by application  
8 to your Honor.

9 MR. WEISS: We would not agree to that, your Honor.  
10 And Endo has had a de facto TRO since we were before your Honor  
11 on, I think, August 26th, and Actavis was ready to go then.  
12 And to allow the Court the opportunity to have briefing and  
13 hearing on this issue, which the Court thought could be  
14 dispositive and which the parties agreed would make sense, the  
15 company did not start selling its product. Now --

16 THE COURT: What is your calendar -- your company's  
17 calendar now?

18 MR. WEISS: They are ready to go today.

19 And we were ready to go a month ago, or three/four  
20 weeks ago. And there was never an application made by Endo for  
21 a TRO.

22 And to now ask for -- I mean, there is nothing to  
23 stay. It's not as if the Court granted an injunction and I  
24 asked for a stay. There is nothing --

25 THE COURT: Let me just ask to backtrack.

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1 The lawsuit was filed when?

2 MR. WEISS: In 2012.

3 THE COURT: All right. And is it correct that by  
4 virtue of the circumstances that existed as time went on, it  
5 was agreed that the first thing to be heard was the preliminary  
6 injunction motion; is that right?

7 MR. WEISS: Mostly what was agreed, your Honor, after  
8 Endo filed the preliminary injunction motion --

9 THE COURT: When did they file it?

10 MR. WEISS: August 6th --

11 THE COURT: All right.

12 MR. WEISS: -- or 5th.

13 What was agreed when we had a conference in front of  
14 your Honor the day that we filed our opposition papers, which I  
15 believe was August 26th, that Monday, what was agreed was that  
16 it would make sense to go forward at that point on the license  
17 issue. Your Honor commented, well, why is this a preliminary  
18 injunction, validity just needs a trial, and your Honor  
19 suggested that the license issue could be dispositive at least  
20 for a preliminary injunction. And the parties agreed that that  
21 made sense.

22 And we had the hearing in chambers, because there were  
23 strangers in the room and there was some confidential  
24 information. And I mentioned to your Honor that we had been  
25 waiting. And you said, well, give notice if you're going to

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1 launch. We can work all night if we have to. And be  
2 reasonable. And don't agree to a briefing schedule that you  
3 can't live with. So we agreed to this briefing schedule for  
4 hearing the license issue.

5 And Endo, you know, has known about this. We've had  
6 final approval from the FDA since July. And there was no  
7 motion for a TRO filed. Endo has not even answered our  
8 invalidity case. They could have. They could have. They did  
9 not. They chose to go forward just on this also. They were  
10 not prohibited from answering that. And they never made an  
11 application for a TRO.

12 And so to now ask for a TRO without an application  
13 having been filed, with what we think is a compelling lack of  
14 irreparable harm shown in our papers -- now, your Honor has not  
15 considered that, I know, because we were doing the license  
16 issue -- to ask for a TRO now, to wait until the PI is denied  
17 and ask for the first time for a TRO, without bond, without  
18 security, is not right. And so we would not agree to that,  
19 your Honor.

20 THE COURT: Look, let me just say this.

21 As Mr. Weiss says -- and the record certainly shows --  
22 I felt, after hearing about the issues quite extensively, I  
23 felt that the license issue was a threshold issue, and that if  
24 the defense won on the license issue, that would be grounds in  
25 and of itself for denying a preliminary injunction.

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1 I did not know at that time how that would come out.  
2 Obviously, if it would come out differently, we would have gone  
3 on to the hearing on invalidity and so forth. However, I have  
4 ruled as I've ruled.

5 Endo has a right to appeal from a denial of a  
6 preliminary injunction, and they certainly have said that they  
7 will do that, and that is their right.

8 If I deny -- the request basically is -- I think  
9 you're right -- I haven't granted any affirmative relief, so it  
10 isn't a matter of staying affirmative relief, it's really to  
11 grant for the first time a restraint, which I have not granted  
12 before and I don't think has even been requested of me. Now  
13 for the first time, after this ruling, there is a request for a  
14 restraint, and one could call it a temporary restraining order,  
15 I suppose.

16 MR. BLACK: May I say something, your Honor?

17 THE COURT: Yes.

18 MR. BLACK: What we're seeking is leave to appeal, to  
19 the extent it is necessary. I think it probably -- leave is  
20 not probably necessary because a denial of a preliminary  
21 injunction is appealable, and also that we maintain the status  
22 quo for one week so that we can file our appellate papers and  
23 let the Federal Circuit hear the issue before the status quo is  
24 changed.

25 Up until now there has been no need for a TRO because,

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1 by agreement of the parties and by informal instruction by your  
2 Honor in chambers, there had been no launch. The question now  
3 on a TRO is whether or not, using the four-factor test, the  
4 irreparable harm and the other factors involved, and looking at  
5 an injunction, whether keeping the status quo in position for  
6 one more week, when they filed this FDA request five years  
7 ago -- five years ago they applied to sell these dosage  
8 strengths -- the question is whether or not we should have one  
9 more week of --

10 THE COURT: I don't understand why it's only one week.  
11 Maybe I don't understand your application.

12 MR. BLACK: We are going to file a motion for  
13 expedited appeal, your Honor, also. We want a --

14 THE COURT: But are you asking me to stay their  
15 marketing pending --

16 MR. BLACK: Yes, your Honor.

17 THE COURT: -- the outcome of the appeal?

18 MR. BLACK: Pending the outcome of the appeal, yes,  
19 your Honor, we have to request that, and, secondarily, pending  
20 the outcome of the Federal Circuit decision on an expedited  
21 motion to maintain the status quo.

22 THE COURT: I am a little confused about what you --

23 MR. BLACK: We have two requests, your Honor. The  
24 first request is to stay your Honor's decision and maintain the  
25 status quo through the conclusion of an expedited appeal.

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1 THE COURT: And what is the second application?

2 MR. BLACK: The second application would be to  
3 maintain the status quo for long enough for us to get our  
4 papers on file and a motion for a restraining order with the  
5 Federal Circuit to decide it, which would be a couple of weeks.

6 THE COURT: Well, back to you, Mr. Weiss.

7 MR. WEISS: So the application, I mean, we're talking  
8 about maintaining the status quo. There is really no such  
9 thing that exists in the rules.

10 What the application is, it's an application for an  
11 injunction pending appeal. And that can be granted by your  
12 Honor, it could be granted by the Circuit Court. But it is  
13 effectively asking for a TRO when none was requested. And it  
14 certainly must be a higher standard than staying an injunction.  
15 To stay an injunction there must be a finding of a likelihood  
16 of success on the merits above, at the Circuit Court, plus the  
17 other factors. And there has been no such showing made here.

18 And so an injunction pending appeal after the  
19 preliminary injunction was denied and when no application for a  
20 TRO was ever made, the standards are not remotely met.

21 It should be denied. If they want to make the  
22 application to the Circuit Court, they certainly can. I think  
23 that will be denied, but I'm not, you know, in a position to  
24 predict what the Circuit Court will do.

25 But there was no application. The standard is not

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1 met. The irreparable harm is not shown. The irreparable harm  
2 that was argued in their brief was four or five generics. What  
3 we're talking about here are two, Actavis and Roxane. I don't  
4 know if Roxane is ready to go or not, they are not my client.  
5 I can speak only for Actavis.

6 THE COURT: What does Roxane say about this?

7 MR. CLEMENT: Roxane doesn't believe there is any need  
8 for a stay pending appeal. Roxane has told Endo that they  
9 would give 30 days notice of any launch. We have not yet given  
10 that notice, although Roxane would like that right to give it  
11 tomorrow should they desire.

12 I don't think that there are grounds for this  
13 injunction pending appeal for precisely the reasons  
14 Mr. Weiss -- I mean, Actavis is out there already selling  
15 product on two of the strengths. They have been selling it for  
16 a number of years. Are they saying that Actavis -- what are  
17 they saying? There are impasses out there. There are a number  
18 of generics already out there. I mean, usually something like  
19 this is done when there are no generics out on the market and  
20 they are afraid to upset the apple cart. This is not the  
21 situation here.

22 THE COURT: Well, it seems to me the way to maintain  
23 the status quo is to maintain the status quo, and that means  
24 that the products that we discussed here, some of them have  
25 been marketed, others will be added to the marketing, but



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that's the status quo, and so any further order by this Court  
is denied.

All right. Thank you.

MR. CLEMENT: Thank you, your Honor.

- - -